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Re-evaluation Note

REV2014-01

Special Review of Aminopyralid: Proposed Decision for Consultation

(publié aussi en français)

24 April 2014

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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ISSN: 1925-0630 (print)
1925-0649 (online)

Catalogue number: H113-5/2014-01E (print version)
H113-5/2014-01E-PDF (PDF version)

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1.0 Introduction

Pursuant to subsection 17(2) of the *Pest Control Products Act*, the Pest Management Regulatory Agency (PMRA) initiated a special review of pest control products containing aminopyralid, based on the Norwegian decision to prohibit the use in Norway due to environmental concerns.¹ The PMRA's initiation of the special review of aminopyralid was announced in December 2013.²

Pursuant to subsection 18(4) of the *Pest Control Products Act*, the PMRA has evaluated the aspect of concern that prompted the special review of aminopyralid. The aspect of concern is relevant to the environment and was identified as the potential for aminopyralid to leach to groundwater.

2.0 Description of Registered Uses in Canada

Aminopyralid is an herbicide, first registered in Canada in 2006. Aminopyralid is currently registered for use in Canada for the control of broadleaved weeds and woody plants in rangeland, pasture, industrial and other non-crop areas, as well as broadleaved weeds in wheat (spring and durum) in the brown soil zone region of western Canada. Aminopyralid is applied using ground or aerial equipment. Appendix I lists all aminopyralid products that are currently registered under the authority of the *Pest Control Products Act*.

3.0 Aspect of the Pest Control Product that Prompted the Special Review

The use of aminopyralid as a pesticide in Norway was prohibited in 2011 due to environmental concerns. The Norwegian assessment indicated that aminopyralid was mobile in soil, persistent in water/sediment and may reach groundwater in concentrations above the Norwegian limit of 0.1 µg/L for pesticides in groundwater.^{3,4} The expected effect of the Norwegian regulatory action was identified as "reducing the risk of groundwater contamination of aminopyralid." The reasons for the Norwegian regulatory action as outlined in the Rotterdam Convention Prior Informed Consent Circular XXXIII were summarised as follows:

"Aminopyralid is highly mobile in soil and will easily be washed down to lower layers of soil and groundwater. Both laboratory studies and model simulations give clear indications of this. Model simulations with the EU [European Union] FOCUS scenarios as well as Norwegian and Swedish groundwater scenarios show that aminopyralid will reach groundwater in concentrations above the threshold of 0.1 µg/L. In addition, aminopyralid is very persistent in water/sediment tests with an average half-life that clearly exceed the EU criteria for persistence in water."

¹ Norway, 2011. Rotterdam Convention, Secretariat for the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, *PIC Circular XXXIII – June 2011*.

² Canada, 2013. Pest Management Regulatory Agency. REV2013-06, *Special Review Initiation of 23 Active Ingredients*.

³ Norway, 2010. Norwegian Scientific Committee on Food Safety. *Evaluation of the Plant Protection Product Simplex – Aminopyralid and Fluroxypyr Regarding Application for Authorisation*.

⁴ Norway, 2010. Norwegian Scientific Committee for Food Safety. *Environmental Risk Assessment of the Pesticide Simplex with the Active Substances*.

Based on the review of the Norwegian decision, the PMRA has defined the aspect of concern that prompted the special review of aminopyralid as the potential for aminopyralid to leach to groundwater.

4.0 Pest Management Regulatory Agency Evaluation of the Aspect of the Pest Control Product that Prompted the Special Review

In order to evaluate aminopyralid's potential for leaching to groundwater, the PMRA has considered available relevant scientific information, which includes information considered for the registration of aminopyralid in Canada,⁵ as well as any relevant information obtained since registration (for example, environmental fate information from laboratory and field studies, available Canadian and American groundwater monitoring data, groundwater modelling based on currently registered Canadian uses, and information from the Canadian incident report database).

Aminopyralid is highly soluble in water (2.48g/L at 18°C), has a low *n*-octanol–water partition coefficient (K_{ow}) and partitions predominantly to the water phase. Aminopyralid does not hydrolyze in water. In laboratory studies, phototransformation in water was rapid (half-life of 0.6 days); however, slower phototransformation is expected under environmental conditions due to cloud cover, light interception by suspended matter and attenuation in deeper water.

Aminopyralid is persistent under aquatic conditions based on aerobic and anaerobic biotransformation studies (half-life of 462–990 days in aerobic systems; stable under anaerobic system). Although aminopyralid is persistent in aquatic systems, entry to the aquatic environment is expected to be limited based on its terrestrial fate and use pattern.

Based on the laboratory studies of transformation, aminopyralid is classified as non-persistent to slightly persistent in most soils (half-life of 6–39 days), but can be persistent in others. No major transformation products are formed in the terrestrial environment. Aminopyralid is not expected to volatilize under field conditions based on its vapour pressure and Henry's Law constant.

Based on aminopyralid's organic carbon partition coefficient (K_{oc} values below 50) from laboratory studies, aminopyralid is expected to be mobile in soil. Terrestrial field dissipation of aminopyralid was also studied in Canadian (New Brunswick, Ontario, Manitoba, Saskatchewan and Alberta) and American (Montana) field trials. Field dissipation was rapid, and aminopyralid is classified as non-persistent to moderately persistent under terrestrial field conditions (DT_{50} values were 9–54 days). The main routes of dissipation in the field are expected to be due to mineralisation and leaching. While aminopyralid can move through the soil profile, leaching to groundwater is expected to be mitigated under actual use conditions due to interception by ground cover and aminopyralid's rapid biotransformation in soil.

The potential for ground water leaching under Canadian use conditions was assessed using modelling. Estimated environmental concentrations of aminopyralid in groundwater were calculated using the Leaching Estimation and Chemistry Model, which simulates leaching through soil profile over a multi-year period (20 years). Conservative assumptions with respect to environmental fate, application rate and timing, and geographic scenario were used. Based on the groundwater modelling, the acute and chronic estimated environmental concentrations for aminopyralid in groundwater are 66.7 µg a.i./L.

⁵ Canada, 2007. Pest Management Regulatory Agency. REG2007-01, *Aminopyralid*.

Any available groundwater monitoring data was also considered. No Canadian groundwater monitoring data on aminopyralid is available; however, American monitoring data are available from the state of Montana. The highest aminopyralid level detected in groundwater is 1.8 µg/L.

Additional information submitted to the PMRA, including incident reports in the Canadian database, was also reviewed for purposes of the special review of aminopyralid. No additional information related to the aspect of concern was identified.

To minimize the potential leaching to groundwater and contamination of aquatic systems, the labels of all currently registered end-use products containing aminopyralid in Canada include precautionary measures. These environmental risk reduction measures include precautionary statements pertaining to leaching and surface runoff, as well as spray drift buffer zones.

5.0 Drinking Water Risk Assessment

In addition to reviewing the potential for aminopyralid to reach groundwater, the PMRA has conducted a scientifically based drinking water risk assessment to determine whether exposure to aminopyralid through Canadian groundwater presents an unacceptable risk to Canadians. The estimated level of aminopyralid in groundwater (66.7 µg a.i./L) under Canadian use conditions was incorporated into the PMRA dietary risk assessment to assess the potential risk from exposure through drinking water. Aminopyralid is of low acute toxicity and no acute reference dose was identified for any population. Chronic dietary exposure to aminopyralid from food and drinking water constitutes 0.3–1.0% of the acceptable daily intake of 0.5 mg/kg bw/day for all population subgroups and is below the level of concern.

The Norwegian *Drinking Water Regulations* (Regulation No. 1372) set quality standards for drinking water in Norway including a threshold of 0.1 µg/L for any individual pesticide in water intended for human consumption. The 0.1 µg/L threshold is a legislated value that applies to all pesticides regardless of their toxicity to humans. The PMRA follows a scientific approach in determining the risk to human health from pesticides in drinking water. This approach takes into consideration both the estimated level in drinking water sources and the toxicity of the pesticide. Based on the drinking water risk assessment of aminopyralid, the PMRA concludes that there are no acute or chronic risks of concern from groundwater under the current conditions of use.

6.0 Proposed Special Review Decision for Aminopyralid

Evaluation of available scientific information related to the aspect of concern, in other words, the potential of aminopyralid to leach into groundwater, indicated that aminopyralid does not pose unacceptable risks to human health or the environment, taking into account current conditions of use. On this basis, the PMRA, under the authority of the *Pest Control Products Act*, is proposing to confirm the current registration of aminopyralid products for sale and use in Canada. This proposal affects products (both technical and end-use products) containing aminopyralid registered in Canada.

This proposed special review decision is a consultation document.⁶ The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information on the cover page of this document).

7.0 Next Steps

Before making a special review decision on aminopyralid, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a special review decision document, which will include the decision, the reasons for it, a summary of the comments received on the proposed decision and the PMRA's response to these comments.

⁶ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

Appendix I Registered Products Containing Aminopyralid as of 7 April 2014

Registration Number	Marketing Class	Registrant	Product Name
28136	Technical	Dow Agrosciences Canada Inc.	AMINOPYRALID TECHNICAL HERBICIDE
28137	Commercial	Dow Agrosciences Canada Inc.	AMINOPYRALID HERBICIDE
28517	Commercial	Dow Agrosciences Canada Inc.	MILESTONE HERBICIDE
28522	Commercial	Dow Agrosciences Canada Inc.	DE-750 HERBICIDE
28551	Commercial	Dow Agrosciences Canada Inc.	RESTORE A HERBICIDE (A COMPONENT OF RESTORE HERBICIDE TANK-MIX)
29745	Commercial	Dow Agrosciences Canada Inc.	GF2050 HERBICIDE
29751	Commercial	Dow Agrosciences Canada Inc.	RECLAIM A HERBICIDE
29752	Commercial	Dow Agrosciences Canada Inc.	CLEARVIEW HERBICIDE
30062	Commercial	Dow Agrosciences Canada Inc.	RECLAIM II A HERBICIDE (A COMPONENT OF RECLAIM II HERBICIDE)
30409	Commercial	Dow Agrosciences Canada Inc.	SIGHTLINE A HERBICIDE
30632	Commercial	Dow Agrosciences Canada Inc.	RESTORE II HERBICIDE

References

Published Information

PMRA Document Number	Reference
2406356	Canada, 2007. Pest Management Regulatory Agency Regulatory Note REG2007-01, Aminopyralid.
2405939	Canada, 2013. Pest Management Regulatory Agency Regulatory Note REV2013-06, Special Review Initiation of 23 Active Ingredients.
2406272	Norway, 2010 a. Norwegian Scientific Committee on Food Safety, Evaluation of the Plant Protection Product Simplex - Aminopyralid and Fluroxypyr Regarding Application for Authorisation, DACO: 12.5.
2406271	Norway, 2010 b. Norwegian Scientific Committee for Food Safety, Environmental Risk Assessment of the Pesticide Simplex with the Active Substances Aminopyralid and Fluroxypyr. Opinion of the Panel on Plant Protection Products. DACO: 12.5.
2406273	Rotterdam Convention, 2011. Secretariat for the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, PIC Circular XXXIII - June 2011, DACO: 12.5.

Unpublished Information

PMRA Document Number	Reference
2404790	Montana Department of Agriculture, 2014. Monitoring data from the Montana Department of Agriculture. DACO: 8.6